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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,165	12/12/2001	Chung-Jen Hou	440508/PALL	1832

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EXAMINER
KIM, SUN U

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,165	HOU ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *121201* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The information disclosure statement submitted on 12/12/01 has been considered by the examiner.

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 34 are product by process claims. Claim 1 is indefinite because a crosslinked coating "prepared from" a polymer indicates that all characteristics of polymer would disappear, in particular as the process steps wherein the various ratios between and specific nature of monomers involved as well as the reaction conditions have not been defined. Furthermore, claim 1 refers to a polymer to be used in the preparation of the coated membrane wherein polymer comprises various monomers such as unsaturated monomers. Claim 1 is indefinite whether the polymer is originally formed from such monomers which then no longer constitutes monomers but rather units of the polymer, whether the coating of the membrane is in fact made from the listed monomers rather from a polymer and in particular whether the crosslinked coating will still contain unsaturated monomers and/or units (see page 7, lines 24-27; page 8, lines 8-12). Claims 1, 27-28 and 34 are indefinite whether the claimed coating comprises all three types of monomers (claims 1, 27, 34) or a polysaccharide and two other monomers (claim 28) or whether the coating is prepared from a polymer comprising one type of polymerized monomer and then crosslinked with the two other types of monomers being up till

crosslinking actually in their monomeric form (see page 6, lines 9-14). For the purpose of examination, a crosslinked coating comprises **a crosslinked polymer** which is formed from claimed monomeric units wherein the polymer essentially does not comprise any unsaturated monomeric groups. Claim 4 is indefinite for failing to particularly point out what is considered "hydroxyl-rich" material. Claim 7 is indefinite by the reference to a nonionic monomer in claim 2 which is further defined as an acrylate. The acrylate functionality (propenoate) is considered to be ionic. Recitation of "said acrylic monomer" in claim 16 lacks a positive antecedent basis. Claim 20 is indefinite how the presence of initiator in the composition from which the coating is produced is deducible from the claimed end product. Claim 23 is indefinite for what is meant by "substrate polymer". For the purpose of examination, "substrate polymer" is assumed to mean that the substrate contains polymeric material. Claim 37 is indefinite for failing to particularly point out what is considered to be a "biomolecule". Claims 22 and 41 are indefinite for failing to particularly point out whether the crosslinks are in fact be "traditional" crosslinks between separate polymeric chains or rather be bonds within a co-polymerized network.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 6-18, 20-27, 29-37 and 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,021,160 (hereinafter referred to as Wolpert). Wolpert teaches a negatively charged microporous membrane comprising anionic charge i.e. negative charge modifying copolymer agent i.e. crosslinked coating on a porous membrane including

polyethersulfone or polysulfone (see col. 1, lines 6-15; col. 5, lines 7-16; col. 8, lines 16-20; col. 12, lines 11-15)(claims 23-26). Wolpert further teaches that copolymer agent is synthesized from 2-acrylamido-2-methyl-1-propanesulfonic acid (AMPS) i.e. unsaturated monomer having a negative charged group and either N-(isobutoxymethyl)acrylamide (IBMA) or 2-hydroxyethyl methacrylate (HEMA) i.e. a hydrophilic non-ionic unsaturated monomer with an initiator including ammonium persulfate (see abstract; col. 5, line 20 – col. 6, line 47; col. 7, lines 5-38; Examples in col. 11-20)(claims 1-4, 6-11, 16-18, 20, 29-34, 45-48). Wolpert further teaches that the copolymer agent contacts with the porous membrane and baked i.e. curing to obtain negatively charged membrane (see col. 7, line 5 – col. 9, line 20)(claim 27). Wolpert also teaches that the resulting anionic charge modified microporous membrane is particularly useful for the filtration of fluids, in particular, aqueous liquids including biological or parenteral liquids (see col. 4, lines 27-32) and the membrane disc is clamped in a suitable funnel (see col. 9, lines 30-35)(claim 35). Wolpert also teaches that a solution of Methylene Blue (a cationic dye i.e. positively charged dye) is vacuum filtered through the anionic charged membrane to adsorb the dye (see col. 10, lines 20-38)(claim 36). Claims 1-4, 6-11, 16-18, 20-21, 23-27 and 29-36 essentially differ from the membrane, device and method of Wolpert in reciting combined use of all three types of claimed monomers in preparing polymer. Wolpert does not disclose the combined use of all three types of monomers, but merely states that AMPS advantageously can be crosslinked using IBMA or HEMA (see col. 5, line 20 – col. 6, line 54). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to crosslink both IBMA and HEMA with AMPS to produce strong and water resistant copolymer to treat microporous membrane (see col. 6, lines 50-54). Regarding claims 12-15, Wolpert teaches that a

strongly acidic i.e. anionic or negative charged copolymer solution (see col. 4, lines 24-26). The use of a carboxy-functionalized acrylate is considered an obvious alternative to sulphonic acid functional group in view of limited number of possible choices as described in prior art disclosed in Wolpert (see col. 1, lines 54-57; col. 3, lines 57-61; col. 4, lines 3-5). Regarding claims 22 and 41-48, in the description, the applicant states that nonionic hydrophilic unsaturated monomer are acrylic monomer containing one or more polar groups that contribute hydrophilicity including hydroxy, alkoxy, hydroxyalkyl and amido and the acrylic monomer can be acrylate ester or an acrylamide (see page 5, line 34 – page 6, line 14) and amide-amide crosslinks form as a results of the reaction between two IBMA monomers and that the amide-ester crosslinks form as a result of the reaction of the nonionic hydrophilic monomer, for instance being a hydroxy or alkoxy acrylic monomer e.g. HEMA, with a crosslinking agent such as IBMA (see page 8, lines 13-28). Wolpert teaches that the acrylamide part is ethyleneically unsaturated and copolymerizes to high conversions with other unsaturated monomers, such as AMPS, **by a free radical mechanism** and the butoxymethyl ether part of IBMA reacts by a cationic mechanism with hydroxyls, with another IBMA, or with other alkoxymethyl amides and this trans-etherification, cationic reaction is catalyzed by acids, such as AMPS and IBMA can be considered the isobutyl ether derivative of N-methyloacrylamide (NMA) by itself as well as other alkoxy derivatives of NMA (such as methoxy, ethoxy, propoxy, higher alkoxy and their isomers) also undergo cationic, trans-etherification reactions similar to IBMA (see col. 6, lines 11-29). As noted above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to crosslink both IBMA and HEMA with AMPS to produce strong and water resistant copolymer to treat microporous membrane (see col. 6, lines 50-54) and such

combination of monomers result in amide-amide and amide-ester links by free radical mechanism as suggested by Wolpert (see col. 6, lines 50-54). Regarding claim 37, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the negatively charged membrane to bind any biomolecules having a positive charge to the membrane while filtering liquids including biological liquids (see col. 4, lines 28-32; col. 1, lines 6-10).

7. Claims 5 and 28 (independently) rejected under 35 U.S.C. 103(a) as being unpatentable over Wolpert as applied to claim 4 above, and further in view of European Patent Application No. 474 617 A1 (hereinafter referred to as EP '617). Wolpert teaches a negatively charged microporous membrane as described in above paragraph. Claims 5 and 28 essentially differ from the membrane and method of making the membrane in Wolpert in reciting polysaccharide in a crosslinked coating. EP '617 teaches the use of polysaccharide type surfactant e.g. hydroxypropyl cellulose in the monomer solution making up the coating of negatively charged microporous membrane comprising a porous substrate and a crosslinked coating providing a negative charge (see page 3, lines 16-25; page 3, line 55 – page 4, line 11; page 5, lines 41-44). EP '617 teaches that surfactant refers to a compound which acts to reduce the interfacial surface tension, and to promote adhesion, between the monomer mixture and/or the hydrogel and the support membrane, including those compounds which coat the support membrane by adsorbing thereonto through hydrophobic interactions (see page 3, lines 19-22). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the polysaccharide type surfactant in the monomer solution making up the coating of negatively charged microporous membrane of Wolpert to reduce the interfacial surface tension, and to

promote adhesion, between the monomer mixture and/or the hydrogel i.e. crosslinked polymer and the support membrane as suggested by EP '617.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolpert in view of EP '617 as applied to claim 5 above, and further in view of U.S. Patent No. 5,783,094 (hereinafter referred to as Kraus et al). Claim 19 essentially differs from the membrane of Wolpert in view of EP '617 in reciting dextran as a polysaccharide. Kraus et al teach the use of polysaccharide type composition e.g. dextran, hydroxypropyl cellulose, etc. in membrane coating for filtering biological liquids (see col. 1, lines 9-15; col. 2, line 11-35). It would have been obvious to a person of ordinary skill in the art to select dextran as equivalent polysaccharide surfactant in the in the monomer solution making up the coating of negatively charged microporous membrane of Wolpert in view of EP '617 to reduce the interfacial surface tension, and to promote adhesion, between the monomer mixture and/or the hydrogel i.e. crosslinked polymer and the support membrane.

9. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolpert as applied to claim 1 above, and further in view of U.S. Patent No. 4,455,370 (hereinafter referred to as Bartelsman et al). Wolpert discloses a negative charged membrane and method as described in above paragraph. Claims 38-40 essentially differ from the method of Wolpert in reciting the step of contacting electrophoresis gel with the membrane and transferring positively charged biomolecules. Bartelsman et al teach the known use of microporous membrane for transferring nucleic acids or proteins from an electrophoresis gel to a microporous adsorptive membrane (see col. 2, lines 31-39). Wolpert teaches the use of negatively charged membrane to absorb cationic atoms i.e. positive charge atoms to the membrane from liquids including

biological liquids (see col. 4, lines 28-32; col. 1, lines 6-10). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the negatively charged membrane to transfer biomolecules having a positive charge to the negatively charged membrane by contacting the membrane with electrophoresis gel.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim
Primary Examiner
Art Unit 1723

J. Kim
September 23, 2003